## REMARKS

This amendment is responsive to the Office Action dated February 21, 2007. Claims 1 - 16 are pending in this application and have been rejected. Reexamination is respectfully requested in view of the foregoing amendments to the claims and following remarks.

### Claim Rejections - 35 USC § 112

Claims 1 - 16 have been rejected under 35 USC § 112 (second paragraph) as being indefinite. All of the claims discussed by the examiner have been amended to overcome the rejections under 35 USC § 112.

Claim 1 now recites a plurality of sections rather than intended use. In claims 4 - 8, "a" has been changed to "the" for clarity. Claims 2 - 3 have been canceled. Claim 5 has been amended to make it clear that it is the label product that contains the metallic colloidal particle or a latex particle. Claim 8 has been amended to refer to a capture section. The term base has been deleted. Claims 9 - 16 have been canceled.

### Introduction - The Prior Art Rejection

The instrument claimed in claims 1 - 2, 4 - 8 and 17 - 21 corresponds to the detection instrument B which is disclosed in

the specification on pages 25 to 36 and 42 to 50, and Figures 3 and 4.

The present invention is based on the findings that, when a test sample is reacted with a label product in advance to obtain a reaction product, and then the reaction product is applied to immunochromatography, a target substance, dioxins and/or PCB/s in the test sample can be detected with extremely high sensitivity.

In conventional immunochromatography, a test sample is applied on a chromatography instrument, on which a labeled antibody which is in advance set in unbound or bound condition, and reacted with the labeled antibody, the resultant reaction product is mobilized on the chromatography to detect a target substance. In contrast, the immunochromatography according to the present claimed invention requires that a labeled antibody is in advance reacted with a test sample outside the chromatography instrument, and that the resultant reaction product is applied on chromatography to detect a target substance, dioxins and/or PCBs. In the claimed immunochromatography, dioxins and/or PCBs can be detected with ten or more fold sensitivity compared with a case where a reaction with a test sample and a labeled antibody is carried out on chromatography. This is demonstrated in the examples in the specification (comparison between Table 2 and Table 3, comparison between Table 4 and Table 5, etc.).

US Patent 5,451,504 cited in the Office Action does not disclose that a test sample is reacted with a labeled antibody in

advance, and the reaction product is applied on immunochromatography to detect dioxins/or PCBs, or that detection sensitivity of dioxins or PCBs is dramatically improved by reaction with test sample with a labeled antibody outside immunochromatography.

Claim 1

Amended claim 1 is directed to a low-molecular-weight substance detection instrument employing immunochromatography, comprising a reaction product contact section, an unbound label product capture section and a detection section, for detecting a dioxin and/or a PCB in a test sample. The instrument of amended claim 1 relates to Fig. 3 of this application, and does not contain a section that contains unbound label product, i.e., a label product reaction section. Illustration for the detection instrument of amended claim 1 is attached for the examiners consideration.

In the detection instrument of amended claim 1, a reaction product which has previously formed through contact between a test sample and a label product is applied to the detection instrument, rather than the test sample per se being applied. When the reaction product previously formed is applied to the detection instrument, detection sensitivity of a dioxin and/or a PCB in a test sample is dramatically enhanced, through the fact that the unbound label product can be prevented from rapidly

reaching the unbound label product capture section, whereby false-positive reaction as discussed on page 25 of the specification is suppressed.

In contrast, in the apparatus disclosed in Fitzpatrick et al. (US 5,451,504), a test sample is applied and an analyte in the sample is bound to a mobilizeable receptor to form a receptor-analyte complex in the first zone. Fitzpatrick et al. does not describe that the receptor-analyte complex has been previously formed and applied to the apparatus, or that detection sensitivity is dramatically enhanced by forming the receptor-analyte complex and applying the complex to the apparatus.

The target substance for the detection instrument of amended claim 1 is dioxins or PCBs. Fitzpatrick et al. describes examples of the analyte in column 4, lines 16-25, which does not contain dioxins or PCBs.

In the present invention, a target substance, a dioxin or a PCB, is bound to a label product to form antigen-antibody complex outside immunochromatography, and the complex is applied to immunochromatography, whereby high sensitivity can be realized. Fitzpatrick et al. does not describe or mention that antigen-antibody complex is formed outside immunochromatography, or that dioxins or PCBs can be detected at high sensitivity by applying the antigen-antibody complex (formed outside) to immunochromatography. The detection sensitivity of the detection instrument of new claim 1 is higher by a factor of 10 or more

that that of a conventional instrument such as the apparatus disclosed in Fitzpatrick et al., as seen from comparison between Tables 2 and 3.

Dependent Claims

Claim 4 contains additional definition of the unbound label product capture section and the detection section, i.e., claim 4 defines that the unbound label product capture section contains an element which captures the label product which is not bound to the target substance, which element is bound to the unbound label product capture section, and the detection section contains a detection element.

Regarding amended claim 5, the label product contains an antibody capable of binding to a target substance in a test sample, and a labeling substance such as a metallic colloidal particle or a latex particle.

Claim 6 contains additional definition of a detection element.

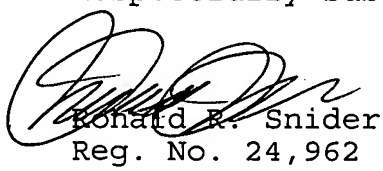
In new claim 17 a reaction step of a test sample with a label product is added to make clear the use method of the detection instrument of claim 1. Claim 18 contains more definition of the detection step. In claim 19, in order to detect a target substance by use of the detection instrument, a label product which is not bound to a target substance may be detected as a negative index, as described in page 36 of the

specification.

In order to avoid confusion, new claim 17 contains a step for detecting a target substance bound to a label product, and new claim 19 contains an additional step for detecting a label product that is not bound to a target substance. New claim 20 and 21 are prepared based on claims 18 and 19 prepared by you.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action in accordance thereof is requested. In the event there is any reason why the application cannot be allowed in this current condition, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems by Interview or Examiner's Amendment.

Respectfully submitted,



Ronald R. Snider
Reg. No. 24,962

Date: August 16, 2007

Snider & Associates
Ronald R. Snider
P.O. Box 27613
Washington, D.C. 20038-7613
Tel.: (202) 347-2600

RRS/bam